II. Listing of Claims

Claim 1. (Previously Presented) A process for the preparation of an agglomerated solid dosage form, comprising

(1) preparing an aqueous slurry of

(a) microcrystalline cellulose;

(b) a microcrystalline cellulose compressibility augmenting agent which

(I) physically restricts the proximity of the interface between adjacent cellulose surfaces;

(ii) inhibits interactions between adjacent cellulose surfaces, via the creation of a hydrophobic boundary at cellulose surfaces; or

(iii) accomplishes both (I) and (ii) above;

(c) an active agent; and

(d) an effective amount of a sustained release carrier;

(2) thereafter spray drying the resultant aqueous slurry in a manner which inhibits quasi-hornification, thereby obtaining agglomerated particles which are directly compressible into a solid sustained release matrix which provides release of the active agent over a time period of about 8 to about 24 hours.

Claim 2. (Previously Presented) The process of claim 1, further comprising compressing the agglomerated particles into a tablet.

Claim 3. (Previously Presented) The process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB of at least about 10.

Claim 4. (Previously Presented) The process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB of at least about 15.

Claim 5. (Previously Presented) The process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB from about 15 to about 40.

Claim 6. (Previously Presented) The process of claim 5, wherein said compressibility augmenting agent is sodium lauryl sulfate.

Claim 7. (Previously Presented) The process of claim 5, wherein said compressibility augmenting agent is a polysorbate.

Claim 8. (Previously Presented) The process of claim 1, wherein said compressibility augmenting agent further comprises a silicon dioxide having an average primary particle size from about 1 nm to about 100 μm.

Claim 9. (Previously Presented) The process of claim 8, wherein said silicon dioxide is included in amount from about 0.1% to about 20% by weight, based on the weight of microcrystalline cellulose.

Claim 10. (Previously Presented) The process of claim 3, wherein said surfactant is included in amount from about 0.1% to about 20% by weight, based on the weight of microcrystalline cellulose.

Claim 11. (Previously Presented) The process of claim 9, wherein said silicon dioxide is colloidal silicon dioxide.

Claim 12. (Cancelled)

Claim 13. (Previously Presented) The process of claim 1, wherein said sustained release carrier is selected from the group consisting of an alkyl cellulose, an acrylic polymer or copolymer, a cellulose ether, a cellulose ester, and mixtures thereof.

Claim 14. (Previously Presented) The process of claim 1, wherein said sustained release carrier is selected from natural or a synthetic gums.

Claim 15. (Previously Presented) The process of claim 1, further comprising adding a film forming agent into the aqueous slurry, and drying the aqueous slurry in such a manner as to obtain agglomerated particles having a film coating.

Claims 16-17. (Cancelled)

Claim 18. (Previously Presented) The process of claim 15, further comprising compressing the agglomerated particles into tablets.

Claim 19. (Previously Presented) The process according to claim 1, wherein the aqueous slurry has a solids content from about 0.5 to about 25%, by weight prior to said spray drying step.

Claim 20. (Previously Presented) The process according to claim 1, wherein the aqueous slurry has a solids content from about 15 to about 20%, by weight prior to said spray drying step.

Claims 21-31 (Cancelled)

Claim 32. (Previously Presented) The product according to claim 1.

Claim 33. (Previously Presented) The process of claim 1, further comprising admixing a further amount of sustained release carrier with said agglomerated particles and compressing the resulting mixture into tablets.

Claim 34. (Previously Presented) The process of claim 33, further comprising wet granulating said mixture, and then compressing the resulting mixture into tablets.

Claim 35. (Previously Presented) The process of claim 33, further comprising adding a further amount of active ingredient to the mixture.

Claim 36. (Previously Presented) The process of claim 1, further comprising adding a pharmaceutically acceptable filler to the aqueous slurry.

Claim 37. (Previously Presented) The process of claim 36, wherein the pharmaceutically acceptable filler is selected from the group consisting of a monosaccharide, a dissacharide, a polyhydric alcohol, inorganic phosphates, sulfates, carbonates and mixtures thereof.

Claim 38. (Previously Presented) The process of claim 36, wherein the pharmaceutically acceptable filler is selected from the group consisting of sucrose, dextrose, lactose, xylitol, fructose, sorbitol, calcium phosphate, calcium sulfate, calcium carbonate, "off-shelf" microcrystalline cellulose and mixtures thereof.

Claim 39. (Previously Presented) The process of claim 1, wherein said sustained release carrier includes a release modifying agent that alters the release rate of the active agent from the formulation upon exposure to an aqueous medium.

Claim 40. (Previously Presented) The process of claim 39, wherein said release modifying agent is selected from the group consisting of calcium sulfate, sodium chloride, potassium sulfate, sodium bicarbonate, lithium chloride, tripotassium phosphate, sodium borate, potassium bromide, potassium fluoride, sodium bicarbonate, calcium chloride, magnesium chloride, sodium citrate, sodium acetate, calcium lactate, magnesium sulfate and sodium fluoride.

Claim 41. (Previously Presented) The process of claim 1, wherein the slurry includes a plurality of slurries, each of the plurality of slurries containing one of: a) a microcrystalline cellulose; or ii) a microcrystalline cellulose compressibility augmenting agent.

Claim 42. (Previously Presented) The process of claim 1, wherein said sustained release carrier is selected from the group consisting of a polylactide, a polyglycolide, a poly(lactide-co-glycolide), a polyanhydride, a polyorthoester, polycaprolactones, polyphosphazenes, polysaccharides, proteinaceous polymers, soluble derivatives of polysaccharides, soluble derivatives of proteinaceous polymers, polypeptides, polyesters and polyorthoesters.

Claim 43. (Previously Presented) A process for the preparation of a sustained release agglomerated
solid dosage form, comprising

(1) preparing an aqueous slurry of

(a) microcrystalline cellulose;

(b) a microcrystalline cellulose compressibility augmenting agent comprising:

(i) silicon dioxide; or

(ii) a surfactant selected from the group consisting of sodium lauryl sulfate, docusate salts, alkyl carboxylates, acyl lactylates, alkyl ether carboxylates, N-acyl sarcosinates, polyvalent alkyl carbonates, N-acyl glutamates, fatty acids, polypeptide condensates

sulfuric acid esters, polyoxyethylene compounds, lecithin, ethoxylated alcohols, ethoxylated esters, ethoxylated amides, polyoxypropylene compounds, propoxylated alcohols, ethoxylated/propoxylated block polymers, propoxylated esters, alkanolamides, amine oxides, fatty acid esters of polyhydric alcohols, ethylene glycol esters, diethylene glycol esters, propylene glycol esters, glycerol esters, polyglycerol fatty acid esters, sorbitan esters, sucrose esters, glucose esters, simethicone, acacia, benzalkonium chloride, cholesterol, emulsifying wax, glycerol monostearate, lanolin alcohols, lecithin, poloxamer, polyoxyethylene and castor oil derivatives; or

(iii) a highly polar dye selected from the group consisting of 3,3'-[[1,1'Biphenyl]- 4,4'-diylbis-(azo)]bis[4-amino-1-naphthalenesulfonic acid] disodium salt; disodium salt of 6-hydroxy-5[(2-4-sulfophenyl) azo]-2-naphthalenesulfonic acid); 5-oxo-1-(p-sulfophenyl)-4-[(p-sulfophenyl)azo]-2-pyrazoline-3-carboxylic acid, trisodium salt); disodium salt of 1-p-sulphophenylazo-2-naphthol-6-sulfonic acid); trisodium-2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6, 8-disulfonate); disodium 4,4'-(2,4-dihydroxy-5-hydroxymethyl-3,3-phenylene bisazo)di(napthalene-1-sulfonate)); tetrasodium 4-acetamido-5-hyroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo]naphthalene-1,7-disulfonate); disodium 4-hydroxy-3-(4-sulfanato-1- naphythylazo) Naphthalene-1-sulfonate); trisodium 2-hydroxy-1-(4-sulfonato-1- naphthylazo) naphthalene-3, 6-disulfonate) and mixtures thereof; or

(iv) a combination of two ro more of (I), (ii) and (iii) above;

(c) an active agent; and

(d) an effective amount of a sustained release carrier; and

(2) thereafter spray drying the resultant aqueous slurry in a manner which inhibits quasi-hornification, thereby obtaining agglomerated particles which are directly compressible into a solid sustained release matrix which provides release of the active agent over a time period of about 8 to about 24 hours.